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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,682	08/27/2001	David E. Townsend	150026.464	4343

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	10

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,682	TOWNSEND, DAVID E.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1 – 16 in Paper No. 9 is acknowledged.

Claims 17 – 24 have been cancelled, claims 1 – 16 are pending and have been considered on the merits.

Claim Objections

2. Claim 4 is objected to because of the following informalities:

Salmonella, Listeria, Cryptosporidium and Giardia should each be capitalized, "aerus" should be spelled correctly as "aereus", and "cryptsporidium" should be spelled correctly as "Cryptosporidium". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 – 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a composition however are rendered vague and indefinite because it is unclear what applicant intends to include or exclude from the claimed composition. For example, by not specifically defining the target microorganism, substrate and/or enzyme, it is unclear what substrates are required to meet the claim.

Claim 1 and 8 are rendered vague and indefinite for reciting "capable of providing" because it is unclear if the marker/signal moiety must provide a detectable signal, or merely may potentially provide the detectable signal.

In claim 13, "said non-target microorganism" lack sufficient antecedent basis. The claim appears to depend from claim 8 rather than claim 6.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 – 6 and 8 – 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Townsend et al. (WO 96/40980).

Applicant claims a composition comprising a conditionally detectable marker that provides a detectable signal upon contact with a viable microorganism, and a substrate for an enzyme substantially absent from a target microorganism. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aereus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change. The substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The enzyme is aminopeptidase, specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically l-alanine-7-amido-4-methylcoumarin. The non target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (p.11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers include tetrazolium that is chemically reduced to produce a color change (p.2) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p.6, 9), or are conditionally detectable markers. Bacteria are selected from Staphylococcus aureus, E. coli, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p.8-9) (includes Salmonella, Listeria, Camplyobacter, Cryptosporidium, S. aureus). Townsend teaches the claimed substrates (p.19), preferring L-alanine-7-amido-4-

methylcoumarin, and L-alanine-aminopeptidase as the enzyme (p.9). The composition further comprises the nutrients necessary to support growth of the microorganisms (p.3).

Although Townsend does not teach each functional limitation of the claims, the compositions are the same. As such the composition of Townsend must intrinsically exhibit the claimed functional properties. Therefore, the reference anticipates the claimed subject matter.

7. Claims 1 – 3, 6 – 8 and 13 – 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Grant (US 5849515).

Applicant claims a composition comprising a conditionally detectable marker that provides a detectable signal upon contact with a viable microorganism, and a substrate for an enzyme substantially absent from a target microorganism. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria. The conditionally detectable marker is detectable by a color change produced by a biochemical reduction of tetrazolium red. The substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non-target microorganisms wherein non target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms containing all necessary nutrients and growth conditions to support target organism; and antibiotics to suppress growth of non target microorganisms.

Grant teaches a composition for detecting microorganisms in a sample, the composition comprising markers, nutrient substrates, growth medium and antibiotics against non target microorganisms (col.3 line 34 – col.4 line 17). Specifically, the composition targets E.coli, the

marker is tetrazolium red (col.6 line 19-32). The composition further contains chromogenic substrates (capable of providing detectable signals upon cleavage) for non-target coliform microbes (substantially non-Campylobacter species) (col.6 line 23-25).

Although Grant does not teach each functional limitation of the claims, the compositions appear to be the same. As such the composition of Grant must intrinsically exhibit the claimed functional properties. Therefore, the reference anticipates the claimed subject matter.

8. Claims 1 – 7 and 14 – 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Line et al. (US 6368847).

Applicant claims a composition comprising a conditionally detectable marker that provides a detectable signal upon contact with a viable microorganism, and a substrate for an enzyme substantially absent from a target microorganism. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically a bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aereus, Cryptosporidium or Giardia; more specifically Campylobacter. The conditionally detectable marker is detectable by a color change, produced by a biochemical reduction of tetrazolium red. The composition further comprises a growth supporting medium for target microorganisms containing all necessary nutrients and growth conditions to support target organism; and antibiotics to suppress growth of non target microorganisms.

Line teaches compositions for detecting microorganisms, the compositions comprising tetrazolium red, a nutrient medium (or substrate) and antibiotics (abstract). The composition detects Campylobacter.

Although Line does not teach each functional limitation of the claims, the compositions appear to be the same. As such the composition of Line must intrinsically exhibit the claimed functional properties. Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend.

Applicant claims a composition comprising a conditionally detectable marker that provides a detectable signal upon contact with a viable microorganism, and a substrate for an enzyme substantially absent from a target microorganism. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aereus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change, wherein the change in color is produced by a biochemical reduction of tetrazolium red. The substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The enzyme is aminopeptidase, specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically l-alanine-7-amido-4-methylcoumarin. The non-target

microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (p.11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers include tetrazolium that is chemically reduced to produce a color change (p.2) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p.6, 9), or are conditionally detectable markers. Bacteria are selected from Staphylcoccus aureus, E. coli, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p.8-9) (includes Salmonella, Listeria, Camplyobacter, Cryptosporidium, S. aureus). Townsend teaches the claimed substrates (p.19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (p.9). The composition further comprises the nutrients necessary to support growth of the microorganisms (p.3).

Although Townsend does not specifically teach the composition comprising tetrazolium red, Townsend does teach effective markers include tetrazolium. Therefore it would have been well within the purview of one of ordinary skill in the art to use tetrazolium red in the composition of Townsend with a reasonable expectation for successfully detecting microorganisms.

11. Claims 1 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend in view of Stern et al. (US 5891709).

Applicant claims a composition comprising a conditionally detectable marker that provides a detectable signal upon contact with a viable microorganism, and a substrate for an enzyme substantially absent from a target microorganism. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aereus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change, wherein the change in color is produced by a biochemical reduction of tetrazolium red. The substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The enzyme is aminopeptidase, specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically l-alanine-7-amido-4-methylcoumarin. The non-target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism and antibiotics to suppress growth of non target microorganisms.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (p.11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers include tetrazolium that is chemically reduced to produce a color change (p.2) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p.6, 9), or are conditionally detectable markers. Bacteria are selected from Staphylcoccus aureus, E. coli, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p.8-9) (includes Salmonella, Listeria, Camplyobacter, Cryptosporidium, S.

aureus). Townsend teaches the claimed substrates (p.19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (p.9). The composition further comprises the nutrients necessary to support growth of the microorganisms (p.3).

Although Townsend does not specifically teach the composition comprising tetrazolium red, Townsend does teach effective markers include tetrazolium. Therefore it would have been well within the purview of one of ordinary skill in the art to use tetrazolium red in the composition of Townsend with a reasonable expectation for successfully detecting microorganisms.

Townsend does not teach the composition further comprising antibiotics. However, Stern teaches compositions for detecting viable gram negative bacteria comprising antibiotics for suppressing other, non target microorganisms (abstract). Stern teaches the inclusion of antibiotics allows the characterization of the target microorganism (col.1 line 25-36). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Stern to include antibiotics in the composition of Townsend with a reasonable expectation for successfully detecting viable target bacteria.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
June 30, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER